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N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

CENTRAL ADMIXTURE PHARMACY SERVICES, INC., and GERALD BUCKBERG,	)	
Plaintiffs,	)	**CASE NO. CV-00-2430-VEH**
v.	)	
ADVANCED CARDIAC SOLUTIONS, P.C., and CHARLES WALL,	)	
Defendants.	)	

MEMORANDUM OF OPINION

Before the court are four motions for summary judgment, filed by the plaintiffs, Central Admixture Pharmacy Services, Inc. ("CAPS"), and Gerald Buckberg; and two motions for summary judgment and one motion for judgment on the pleadings, filed by the defendants, Advanced Cardiac Solutions, P.C. ("ACS"), and Charles Wall.

The instant cause is a civil action for the infringement of U.S. Patent Number 4,988,515 (the "'515 patent"). The plaintiffs are, Dr. Gerald Buckberg, the inventor and alleged owner of the patent, and CAPS, the exclusive licensee of the patented invention. In their complaint, the plaintiffs assert a cause of action under federal patent law, 35 U.S.C. §§ 281, *et seq.*, against the defendants ACS and Charles Wall

for infringement of the '515 patent by producing, commercially marketing, and selling directly infringing products, and by inducing others to infringe the patent by producing infringing products.

In their Third Amended Answer and Counterclaim, the defendants assert several defenses to the plaintiffs' patent infringement claim as well as three counterclaims of their own. In Counterclaim I, the defendants seek a declaration that the '515 patent is unenforceable and, alternatively, that the defendants did not infringe the patent. In Counterclaim II, the defendants assert a cause of action under 35 U.S.C.A. § 292 for false marking. In Counterclaim III, the defendants assert a cause of action for false advertising under the Lanham Act, 15 U.S.C.A. § 1125(a)(1)(b).

In the instant motions filed by the defendants, the defendants seek judgment on the plaintiffs' claim of infringement on three separate grounds. In the first motion (doc. 219), the defendants seek judgment on the pleadings on the ground that the plaintiffs do not have title to the patent. In the second motion (doc. 233), the defendants move for summary judgment based upon the defense that the plaintiffs engaged in inequitable conduct in the procurement of the patent. In the third motion (doc. 235), the defendants seek partial summary judgment on the ground that the plaintiffs have failed to adduce any evidence that the defendants infringed the '515

patent prior to the issuance of the Certificate of Correction.

In the instant motions for summary judgment filed by the plaintiffs, the plaintiffs seek judgment on their claim of infringement, on the defendants' three counterclaims, and on an unpled counterclaim for violations of the Sherman Anti-Trust Act. In the plaintiffs' first motion (doc. 221), they seek summary judgment on their claim of infringement and against the defendants' counterclaim for a declaration of no infringement. In the plaintiffs' second motion (223), they seek summary judgment on the defendants' defense that the '515 patent is invalid. In the plaintiffs' third motion (doc. 226), the plaintiffs seek summary judgment on the defendants' counterclaim of false marking and false advertising under Lanham Act. In the plaintiffs' fourth motion (doc. 229), they seek summary judgment on the defendants' affirmative defense of inequitable conduct, patent misuse, and on an unpled counterclaim under the Sherman Anti-Trust Act.

These motions were opposed, fully briefed, and were taken under submission by the court on July 26, 2005.

SUMMARY OF DISPOSITION

For the reasons below, the court rules as follows:

1. The defendants' motion for judgment on the pleadings for lack of ownership of the '515 patent (doc. 219) is DENIED;

2. The plaintiffs' motion for summary judgment as to the defendants' claim of inequitable conduct and patent misuse (doc. 229) is GRANTED[1] and the defendants' motion for summary judgment on inequitable conduct (doc. 233) is DENIED;

3. The plaintiffs' motion for summary judgment as to the defendants' claim of that the '515 patent is invalid on grounds of obviousness (doc. 223) is GRANTED;

4. The plaintiffs' motion for summary judgment on its claim of infringement (doc. 221) is DENIED IN PART and GRANTED IN PART as follows: summary judgment is granted as to whether the defendants willfully infringed the '515 patent provided that the certificate of correction is found to be valid; summary judgment is denied as to whether the certificate of correction is valid;

5. The defendants' partial motion for summary judgment of no infringement prior to the issuance of the certificate of correction (doc. 235) is DENIED;

6. The plaintiffs' motion for summary judgment on the second counterclaim of false marking and third counterclaim of false advertising (doc. 226) is GRANTED.

PROCEDURAL BACKGROUND

The plaintiff CAPS commenced this action on August 31, 2000, by filing a complaint with this court asserting a cause of action for patent infringement under federal patent law. Fact discovery in this case initially closed on August 17, 2001.

[1]Because the plaintiffs' motion for summary judgment on the defendants' unpled counterclaim of antitrust violation (doc. 229) is DENIED AS MOOT, the plaintiffs' fourth motion for summary judgment (doc. 229) is GRANTED IN PART as to defendants' defenses of inequitable conduct and patent misuse and DENIED IN PART as to the defendants' unpled antitrust counterclaim. The defendants failed to plead a counterclaim for violations of the federal antitrust laws, and the claim simply is not before the court.

On April 30, 2002, the court conducted a *Markman* hearing to construe the claims of the '515 patent. On May 2, 2002, the court issued its *Markman* order construing the claims of the patent. On November 21, 2003, the plaintiffs filed their motions for summary judgment. On December 8, 2003, the court extended the deadline for filing dispositive motions until March 23, 2004. On March 23, 2004, the date of the dispositive motion deadline, the defendants filed two motions for summary judgment, as well as a motion to dismiss and a motion regarding claim construction. On September 1, 2004, the defendants filed an additional motion for summary judgment on the previously unraised grounds of inequitable conduct and common law fraud, along with a "supplemental" motion for summary judgment on the ground of patent invalidity.

On November 29, 2004, the court entered an order denying the defendants' motion to dismiss for lack of standing. However, the court agreed with the defendants' argument that CAPS, the exclusive licensee of the patented technology, was required to join the inventor, Dr. Gerald Buckberg, as a plaintiff to the action to comply with statutory, as opposed to constitutional, standing requirements. On December 15, 2004, Dr. Buckberg was joined as a plaintiff in the action. On January 7, 2005, the court gave the defendants 60 days to conduct discovery on Dr. Buckberg.

Due to the additional discovery and the passage of time, on March 3, 2005, the

court denied all of the parties' previously filed summary judgment motions. On May 5, 2005, the court required that new motions for summary judgment be filed by June 6, 2005. The parties filed six new motions for summary judgment on the date of the deadline. In addition, on May 23, 2005, the defendants also filed a motion for judgment on the pleadings. On July 26, 2005, the court took those summary judgment motions and the motion for judgment on the pleadings under submission. They are now before the court.

THE TECHNOLOGY

The invention at the heart of this dispute is called a cardioplegic solution. Cardioplegic solutions are chemical solutions used during open-heart and other kinds of stop-heart surgical procedures. One type of cardioplegic solution is used to stop the heart and reduce its energy demands. While the heart is stopped, the patient is sustained on a cardiopulmonary by-pass machine, which maintains the circulation of oxygenated blood through the body. Meanwhile, another cardioplegic solution is used to protect the heart from muscle damage, called ischemia, while the heart is stopped. At the conclusion of the operation, a different cardioplegic solution is infused to start the heart beating again and to prepare the heart for the return of normal blood flow, a process called reperfusion.

THE '515 PATENT

The invention covered by the '515 patent is described as a "cardioplegic solution." Commercially, the invention is known as a "Buckberg Solution" (hereinafter the "Invention" or the "Buckberg Solution") and is named for the inventor, the plaintiff Dr. Buckberg. The patent involves two varieties of cardioplegic solutions: high potassium solutions, which are used initially to stop the heart's beating at the beginning a stop-heart surgical operation, and low potassium solutions, which are used to protect the heart from muscle damage during the surgery. These solutions are called "blood cardioplegic" solutions because the solutions are mixed with the patient's blood before they are infused into the patient's heart.

The '515 invention consists of an amino acid enriched cardioplegic solution with (1) a calcium ion concentration of between 50-300 umol; (2) a concentration of metabolizable substrate between about 400-1000 mg%; and (3) an osmolality of between about 400-500 mOsmol/kg.[2] Because blood usually has a calcium concentration of 1000 umol, a calcium content of 50-300 umol is considered hypocalcemic. Although the patent allows for several varieties of metabolizable

[2]The '515 patent originally provided for the invention to have an *osmolarity* of between about 400-500 mOsmol. On January 30, 2001, the United States Patent and Trademark Office issued a certificate of correction changing every instance of osmolarity in the '515 patent to osmolality. Although the question of the certificate of correction's validity is centrally disputed in this action, for purposes of providing the background of the dispute, the court refers to the '515 patent as altered by the certificate of correction.

substrates, the metabolizable substrate used most often appears to be glucose. A solution having a concentration of glucose between about 400-1000 mg% would fall within the '515 patent's second criterion. Osmolality refers to the number of particles of solute per kilogram of water in the solution and is denoted by the abbreviation mOsmol/kg.[3] Because blood usually has an osmolality of approximately 280-300 mOsmol/kg, the levels of osmolality in described by the '515 patent (between about 400-500 mOsmol/kg) are considered moderately hyperosmotic.

In addition, because the Buckberg Solution is an amino acid enriched solution, it contains 10-30 mmol of the amino acid aspartate and 10-30 mmol of the amino acid glutamate. The solution must have a pH of between 7.5 and 7.7. The Buckberg Solution generally contains blood, but the '515 patent covers solutions involving a "carrier" or "cardioplegic compatible diluent" other than blood as well. However, for the purposes of this action, the only relevant carrier or diluent involved is blood.

The '515 patent has three independent claims: claims 1, 7, and 13. Claim 1has seven dependent claims (Claims 2-6, 18) and patents specific types of cardioplegic solutions. Claim 7 has five dependent claims (Claims 8-12) and patents methods for treating hearts with cardioplegic solutions. Claim 13 has four dependent claims

[3]Osmolarity, by contrast, refers to the number of particles of solute per liter of solution and is denoted by the abbreviation mOsmol/L.

(Claims 14-17) and patents concentrated aqueous solutions that need to be diluted to become cardioplegic solutions. As mentioned above, for purposes of this action, the concentrated aqueous solution referred to in Claim 13 will be diluted with blood to become a cardioplegic solution.

Under all three of the '515 patent's independent claims, the solution, the treatment, and the aqueous solution adapted to be diluted must contain (1) a calcium ion concentration of between 50-300 umol; (2) a concentration of metabolizable substrate between about 400-1000 mg%; and (3) an osmolality of between about 400-500 mOsmol/kg.

I.
Ownership of the '515 Patent

The defendants moved for judgment on the pleadings on the ground that the plaintiffs do not own the '515 patent. The facts relevant to this motion are set out below.

A. *Facts*

Dr. Buckberg created the Buckberg Solution at some point between 1979 and 1985. During this period, Dr. Buckberg was an employee of the University of California. He developed the solution while conducting research pursuant to National Institutes of Health ("NIH") research grant number HL-16292. On August 2, 1985, Dr. Buckberg conveyed his interest in the Buckberg Solution to the University of

California.

On August 21, 1985, Dr. Buckberg applied for a patent on the Buckberg Solution. In the patent application, Dr. Buckberg named himself as the inventor. On December 13, 1985, the Regents of the University of California granted the United States a nonexclusive, nontransferable, irrevocable, royalty-free license to use the Buckberg Solution. (Def. Ex. E.)

On March 11, 1987, Dr. Buckberg requested a waiver of patent rights from the NIH. On September 23, 1987, the Assistant Secretary for Health, Dr. Robert E. Windom, issued a waiver of patent rights with respect to the Buckberg Solution. The waiver provided that Buckberg was "free to retain and administer the patent rights to the invention in accordance with the requirements of 37 C.F.R. § 401.9" and that "the inventor shall grant to the government of the United States a nonexclusive, irrevocable, royalty-free license to use the invention for government purposes." (Def. Ex. G.)

In response to the defendants' requests for admissions, Dr. Buckberg admitted that he "did not execute a license to the United States Government in the invention covered by US Patent 4,988,515 at any time between 1987 and 1991." (Def. Ex. I.)

On January 29, 1991, the PTO issued patent '515, which covered the Buckberg Solution. (Def. Ex. C.) The '515 patent lists Dr. Buckberg as the inventor and the

Regents of the University of California as the assignees. (*Id.*) The '515 patent further provides that "the invention was made with Government support under Grant No. HL 16292 awarded by the National Institutes of Health. The Government has certain rights in this invention." (*Id.*) On June 24, 1991, the Regents of the University of California assigned their rights to the patent to Dr. Buckberg. (Pla. Ex. FFF.)

B. *Legal Standard*

Judgment on the pleadings is proper when no issues of material fact exist and the movant is entitled to judgment as a matter of law. *See Ortega v. Christian*, 85 F. 3d 1521, 1524-25 (11th Cir. 1996).[4]

C. *Analysis*

The defendants' motion for judgment as a matter of law is based on the argument that Dr. Buckberg failed to perfect his title to the invention due to his failure to comply with the Bayh-Dole Act, 35 U.S.C.A. §§ 200-12, the related agency regulations, and the requirements in the NIH's waiver of patent rights that Buckberg execute a license in favor of the United States.[5] (*See* Def. Ex. G.) With respect to the

[4]Because the defendants' motion is based almost entirely upon documents not included within the pleadings, the defendants' motion for the most part is a motion for summary judgment. To the extent that the defendants base their arguments on documents outside the pleadings, the court will evaluate the motion under the standard governing summary judgment set out *infra*.

[5]The defendants also move for judgment on the pleadings on the ground that the plaintiffs failed to specifically allege that Dr. Buckberg owns the '515 patent. Not only is this argument

Bayh-Dole Act, the defendants argue that the Act required Dr. Buckberg to grant the United States a paid-up, irrevocable license to use the Buckberg Solution, and that, because Buckberg failed to do so, he lacks title to the '515 patent.

The Bayh-Dole Act, 35 U.S.C.A. §§ 200-12, governs the patent rights of inventions made with federal assistance. For the act to apply, a party must be a contractor who enters into funding agreements with federal agencies and who reduces to practice an invention, called a subject invention, in the performance of the work under the funding agreement. Here, there is no dispute that the University of California is both a contractor and a nonprofit organization, within the meaning of sections 201(c) and (i) of the Act, and that the Buckberg Solution is a subject invention that was reduced to practice during the performance of work under a funding agreement with a federal agency. The Act therefore applies. The analysis moves to the questions of whether the Act was violated, and if so, what the consequence of the violation must be.

Section 202(c)(1) requires a contractor to disclose within a reasonable time any

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frivolous, but the defendants are estopped from making it. Earlier in the litigation, the defendants moved for dismissal on the basis that Dr. Buckberg, the patent owner, had not been joined as a plaintiff to the action. In course of advancing that argument, the defendants unequivocally asserted that "The patent is owned by Gerald Buckberg." (*See* Defs.' Mot. to Dismiss, doc. 79, at 3.) Having induced the court to order the joinder of Dr. Buckberg on the basis of that argument, the defendants now are estopped from complaining about the inadequacy of the plaintiffs' pleading with regard to Dr. Buckberg's ownership of the '515 patent.

subject invention to the federal agency that issued the funding agreement. *See* 35 U.S.C.A. § 202(c)(1). Federal regulations define a reasonable time as within two months of the date the invention was created. *See* 48 C.F.R. § (c)(1). After the invention is disclosed to the federal agency, the Act requires the contractor to "make a written election within two years after disclosure to the federal agency . . . whether the contractor will retain title to a subject invention." 35 U.S.C.A. § 202(c)(2). If the contractor elects to retain title, section 202(c)(5) provides that "the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practice for or on behalf of the United States any subject invention throughout the world." Federal regulations further require a contractor to "agree to execute or to have executed and promptly deliver to the Federal Agency all instruments necessary to (I) establish or confirm the rights the government has throughout the world in those subject inventions to which the Contractor elects to retain title . . . ." 48 C.F.R. § 52.277(f)(1)(I). The regulations further require the contractor to "include . . . within a patent issuing thereon covering the subject invention, the following statement, 'The invention was made with Government support under (identify the contract) awarded by (identify the Federal agency). The Government has certain rights in the invention.'" *Id.* § 52.277(f)(4).

There is no dispute here that the University of California complied with each

of these requirements. The University timely disclosed the Buckberg Solution to the NIH. On December 13, 1985, it executed a confirmation of the NIH's paid-up, irrevocable license to the invention. (*See* Def. Ex. E.) The '515 patent contains the statement required by regulation section 52.277(f)(4).

However, in 1987, the University of California decided to forgo its rights to the Buckberg Solution. At that point, Dr. Buckberg requested, pursuant to section 202(d) of the Bayh-Dole Act, to obtain the NIH's permission to seek patent rights in his own name. Section 202(d) provides: "If the contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder." 35 U.S.C.A. § 202(d). Among the regulations promulgated under the Act is 37 C.F.R. § 401.9, which provides that "[a]gencies which allow employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business or nonprofit organization, as authorized by 35 U.S.C.A. § 202(d), will impose upon the inventor at least those conditions that would apply to a small business contractor under paragraphs (d)(1) and (3); (f)(4); (h); and (j) of the clause at § 401.14(a)." 37 C.F.R. § 401.9.

On September 23, 1987, the NIH assented to Dr. Buckberg's request to retain

title to what would become the Buckberg Solution. However, the NIH's assent stated that "the inventor shall grant to the Government of the United States a nonexclusive, irrevocable, royalty-free license to the invention for government purposes." The defendants have submitted to the court Dr. Buckberg's admission that he did not execute a such license. Although Rule 37(b) permits a party to move to withdraw or amend an admission, the plaintiffs failed to file such a motion prior to the close of discovery. Consequently, even though Dr. Buckberg has provided, in opposition to this instant motion, a declaration that he did execute a license to the government, under Federal Rule 37(b), the court is obligated to treat Dr. Buckberg's admission as "conclusively establish[ing]" that he did not execute any such license.

The defendants, therefore, have shown that Dr. Buckberg has failed to comply with the Bayh-Dole Act. The question, therefore, moves to what the Act prescribes as consequence of Dr. Buckberg's noncompliance.

The defendants argue that Dr. Buckberg's noncompliance entails that Dr. Buckberg never obtained title to the '515 patent. The problem with the defendants' argument, however, is that this consequence is nowhere mentioned in the Act. Rather, the only consequence mentioned in the Act for failing to comply with its requirements is that the federal government will retain the right to receive title to the invention. For instance, if a contractor entirely fails to disclose the existence of an

invention to the relevant federal agency, the Act provides that "the Federal Government *may* receive title to any subject invention not disclosed to it within such time." 35 U.S.C.A. § 202(c)(1) (emphasis added). Similarly, if a party fails to make a timely written election of its intent to retain title to the subject invention, the Act provides that "the Federal Government *may* receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect within such time." 35 U.S.C.A. § 202(c)(2) (emphasis added). The Federal Circuit has confirmed that the phrase "the Federal Government may receive title" means that the federal government has discretion to determine whether to take title to the invention. *See Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee*, 389 F.3d 1243, 1250 (Fed. Cir. 2004) ("We agree with the [Armed Services] Board [of Contract Appeals] that FAR 52.227.11(d) vests discretion in the government in determining whether to invoke forfeiture when an invention has not been correctly disclosed to it.").

In support of their argument that the Act divests Buckberg of title, the defendants rely on *TM Patents, L.P. v. IBM Corp.*, 121 F. Supp. 2d. 349, 368-69 (S.D.N.Y. 2000). However, the court will not follow *TM Patents* because it is at odds with *Campbell Plastics*. Whereas *Campbell Plastics* states that a violation of the Bayh-Dole Act gives the Federal Government discretion to take title to a subject invention, *see* 389 F.3d at 1250 *TM Patents* states that the forfeiture is automatic. *See*

121 F. Supp. 2d. at 368-69 ("Failure to comply with the conditions of § 202 results in the Government acquiring title."). On this question of patent law, this court is obligated to follow the Federal Circuit's authority as against the Southern District of New York.[6]

Based on the language of the statute and its interpretation by the Federal Circuit, the court determines that Dr. Buckberg's failure to comply with the Bayh-Dole Act leaves the patent subject to the Federal Government's discretionary right to take title to the '515 patent. In addition to the fact that this outcome is supported by the statutory language and applicable case law, the court finds that this conclusion furthers the purpose of the Bayh-Dole Act by interpreting the law to preserve the government's rights to inventions created through government funding and also by declining to interpret the law to provide additional defenses to alleged patent

[6]Furthermore, the *TM Patents* decision is not persuasive because its legal conclusions are not supported by the authorities upon which the decision relies. In support of the proposition that the Bayh-Dole Act operates an automatic forfeiture on the patent rights of parties who do not fully comply with the Act, the *TM Patents* court relies on the following quotation from *Thermalon Industry, Ltd. v. United States*, 34 Fed. Cl. 411, 414 (Fed. Cl. 1995): "NSF [a government entity] acquires title to a patent, rather than a license, *inter alia*, in the event the grantee fails to disclose within a reasonable time that the patented invention resulted from the grant." Although the *TM Patents* court relies on this quotation as an authoritative interpretation of the Bayh-Dole Act, the quotation is no such thing. Instead, the quotation is part of a recitation of the provisions of a contract between the National Science Foundation (NSF) and Thermalon Industries. The *Thermalon* court was not even attempting to construe the Bayh-Dole Act, much less give an authoritative interpretation of it. Indeed, the *Thermalon* case was a breach of contract action for damages having nothing to do with patent rights. Thus, the *TM Patents* opinion is contrary to the language of the Act, contrary to the binding authority of the Federal Circuit, and unsupported by the authority to which it cites.

infringers.

Because the defendants have failed to present any evidence that the NIH has taken title to the '515 patent, the court finds that the defendants are not entitled to judgment on the ground that Dr. Buckberg is not the owner of the patent. Accordingly, the defendants' motion for judgment on the pleadings for lack of ownership of the '515 patent is due to be DENIED.

II.
The Validity of the '515 Patent

The plaintiffs move for summary judgment as to the defendants' counterclaim and affirmative defenses that the '515 patent is invalid.

A. *Summary Judgment Standard*

Under Federal Rule of Civil Procedure 56(c), summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Chapman v. AI Transport*, 229 F.3d 1012, 1023 (11th Cir. 2000). The party asking for summary judgment always bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of the pleadings or filings which it believes demonstrate the absence of a

genuine issue of material fact. *Celotex Corp.*, 477 U.S. at 323. Once the moving party has met his burden, Rule 56(e) requires the nonmoving party to go beyond the pleadings and by his own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial. Id. at 324.

All reasonable doubts about the facts and all justifiable inferences are resolved in favor of the non-movant. *Chapman*, 229 F.3d at 1023; *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1115 (11th Cir. 1993). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Chapman*, 229 F.3d at 1023. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. *Anderson*, 477 U.S. at 249.

On a motion for summary judgment, the burden of proof that applies is the "the evidentiary standard of proof that would pertain at a trial on the merits." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001). Because patents are entitled at law to a presumption of validity, *see* 35 U.S.C.A. § 282, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence of invalidity so that no reasonable jury could invalidate the

patent. *Id.* Additionally, when a party attacks a patent based upon prior art that was considered by the PTO, "he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

B. Facts

As described above, the Buckberg Solution consists of an amino acid enriched cardioplegic solution having (1) a calcium ion concentration of between 50-300 umol; (2) a concentration of metabolizable substrate between about 400-1000 mg%; and (3) an osmolality of between about 400-500 mOsmol/kg. At these levels, the solution combines the characteristics of being hypocalcemic, hyperglycemic, and hyperosmotic, and it possesses these characteristics within the precise ranges claimed in the patent.

The prior art in the area of cardioplegia that form the basis of the defendants' claims of invalidity are as follows. In 1978, Dr. David Follette, *et al.*, published in the journal *Surgical Forum* an article describing a cardioplegic solution that was

hypocalcemic (.5 mEq/L calcium)[7]. The solution described by Dr. Follette was not amino acid enhanced. In 1979, Dr. Buckberg published an article entitled "A Proposed 'Solution' to the Cardioplegic Controversy" in which he disclosed a solution that was hypocalcemic (500 umol calcium) and moderately hyperosmotic (>400 mOsmol/L).

In 1980, in what the parties refer to as the "Dyson Reference," Drs. Buckberg and Charles Dyson described their "standard cardioplegic solution" as being hyperosmotic (360 mOsmol/L) and hypocalcemic with a metabolizable substrate, in this case dextrose, of over 2000 mg%. The Dyson Reference was later updated and, in 1982, it was published as Chapter 22 of the *Textbook on Clinical Cardioplegia* (the "Chapter 22 Reference"). Neither the Dyson Reference nor the Chapter 22 Reference describe solutions that are amino acid enhanced.

In 1981, Dr. David Follette, *et al.*, published an article where the authors described a cardioplegic solution that was hypocalcemic and hyperosmotic, but at various levels of calcium concentration and levels of osmolarity. The article endorses as "ideal" a calcium concentration of 500 umol and an osmotic pressure of 351 +/-5 mOsmol/L. However, the article did not disclose any amount of glucose or other

[7]The defendants' expert, Dr. Robert Riggs, reports that .5 mEq/L converts to 250 umol calcium.

metabolizable substrate in the solution, nor was it amino acid enriched.

In 1982, Dr. Phillip Menasche, *et al.*, published an article wherein the authors disclosed a cardioplegic solution that was hypercalcemic (2500 umol calcium), moderately hyperosmotic (395 mOsmol/L), and hyperglycemic (10 gm/L glucose).[8] Menasche based his solution on a 1981 article by Dr. Follette, although Menasche's solution also was amino acid enriched and contained glucose. The Menasche article described a clinical trial testing a procedure called retrograde coronary sinus profusion as a means of delivering cardioplegia.

In 1983, Dr. Kito published an article describing a cardioplegic solution that was hyperglycemic with a glucose range of 2500-3500 mg%. In 1983, Dr. Rosenkrantz described a cardioplegic solution that was hypocalcemic (500 umol calcium) and moderately hyperosmotic (360 mOsmol/L) but that did not disclose any glucose concentration or recommend amino acid enrichment. In 1984, Dr. Hashimoto disclosed a cardioplegic solution containing 2000 mg% of glucose.[9]

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[8]The defendants' expert, Dr. Riggs, states that 10 gm/L of glucose would produce a glucose concentration of approximately 1000 mg%. (*See* Riggs Decl. (doc. 239, Defs. Ex. 2) ¶ 11.)

[9]Dr. Riggs, the defendants' expert, lists additional references as relevant prior art, but there is no dispute that the remaining references, including the Menasche 1984, the Irasawa 1983, and the Bercot 1979 References disclose cardioplegic solutions that differ in material respects from the Buckberg Solution. Reflecting this, in their brief opposing summary judgment, the defendants make no arguments based upon these additional references.

The application that led to the '515 patent was filed on August 21, 1985. On November 20, 2003, the defendants filed a Request for *Ex Parte* Reexamination of the '515 Patent with the PTO. All of the references cited in the Information Disclosure Statements submitted during the reexamination proceedings were considered by the Examiner. On February 10, 2005, a Notice of Intent to Issue Ex Parte Reexamination Certificate was issued by the Examiner. The Examiner stated that "[n]one of the references, either taken individually or taken as a whole, suggest the cardioplegia solution within the limitations claimed." (*See* Notice of Intent to Issue Reexamination Cert., Pla. Ex. JJ.)

C. *Analysis*

The defendants assert a counterclaim for a declaration that the '515 patent is invalid and raise invalidity as an affirmative defense. The defendants' claims of invalidity are based upon anticipation under section 102 of the patent law, the public use bar under section 102 of the patent law, indefiniteness under section 115 of the patent law, and obviousness under section 103 of the patent law.

1. *Anticipation Under § 102*

"Anticipation under 35 U.S.C.A. § 102 means lack of novelty, and is a question of fact." *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 725 (Fed. Cir. 2002). To prevail on their claim that the '515 patent is void because it was anticipated, the

defendants must show, by clear and convincing evidence, "that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000).

The defendants predicate their claim of lack of novelty on an article authored by Phillip Menasche, *et al.*, published in 1982 in the *Society of Thoracic Surgeons* journal. However, this reference plainly fails to support the defendants' claim of anticipation on two grounds.[10] First, the solution described in the Menasche 1982 Reference discloses a calcium concentration of 2500 umol, which far exceeds the Buckberg Solution's claimed range of 50-300 umol. In fact, the Menasche solution is significantly *hyper*calcemic rather than *hypo*calcemic. Although the defendants argue that a person skilled in the art could add sufficient chelating agent to reduce the calcium concentration to the ranges claimed in the '515 patent, there is nothing in the

[10]The plaintiffs object to the defendants' reliance on this reference because it was not disclosed until three years after the close of the original discovery deadline. Ordinarily, this argument would prevail and the untimely disclosed evidence would be disregarded. *See Sosa v. Airprint Sys., Inc.*, 133 F.3d 1417, 1418 (11th Cir. 1998). However, because the court reopened discovery in this action and permitted the parties to file new motions for summary judgment based upon evidence produced in the most recent round of discovery, the court can see no principled ground for viewing this evidence as untimely, nor can the court perceive that the plaintiffs will suffer any prejudice by the court's consideration of the reference given their opportunity to conduct additional discovery on the reference.

text of the article to motivate a reader to do so. To the contrary, because the article recommends formulating a solution that is strongly hypercalcemic to begin with, it would be contradictory to view the article as disclosing or teaching or in any way encouraging the formulating of a strongly hypocalcemic solution.

Accordingly, the defendants have failed to provide clear and convincing evidence creating an issue of fact as to whether the '515 patent is invalid for having been anticipated. The plaintiffs are entitled to summary judgment on this ground.

2. *Public Use Under § 102*

Section 102 of the patent law provides that a person "shall be entitled to a patent unless . . . (b) the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application in the United States." 35 U.S.C.A. § 102(b). As with any other challenge to the validity of a patent, the burden of proof to prove public use of the patented invention more than a year prior to the filing of the patent application is on the party attacking the patent. *See TP Labs. v. Professional Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984). Furthermore, it is well-established that "if a use is experimental, though not secret, 'public use' is negated." *Id.*

The defendants base their claim of public use on an article that Dr. Buckberg published in 1986 in *The Journal of Thoracic and Cardiovascular Surgery*. The

article reports that, from May 1984 to April 1985, patients were clinically treated at UCLA and Long Beach Memorial Hospital for acute coronary occlusion with a cardioplegic solution within the ranges within the '515 patent. Although Dr. Buckberg testified that he did not remember whether he began treating the patients with the cardioplegic solution before or after August 21, 1984, the defendants ask the court to infer, on the basis of the article, that some use of the cardioplegia occurred prior to this date.

The defendants' reliance on the 1986 article falls short of clear and convincing evidence from which a jury could find that the '515 patent is invalid due to public use. It is well-established that experimental use of an invention does not constitute public use under section 102(b). The fact that Dr. Buckberg published his findings in a scientific journal strongly supports the conclusion that the use was experimental. This conclusion is further supported by the fact that Dr. Buckberg relied on the data obtained from the clinical trials to support his application for a patent on the Buckberg Solution. (*See* '515 patent, at 2.) The defendants offer no evidence contradicting the plain appearance that Dr. Buckberg's clinical use of the invention was experimental.

Accordingly, the plaintiffs are entitled to summary judgment on the defendants' claims that the '515 patent is invalid due to public use under section 102 of the patent

law.[11]

3. *Obviousness Under § 103*

Section 103 of the patent law requires provides that "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C.A. § 103(a). Obviousness is an issue of law based upon four factual inquiries, to wit: "(a) the scope and content of the prior art; (b) the differences between the prior art and the claims at issue; (c) the level of ordinary skill in the art; (d) the objective evidence of nonobviousness." *Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc.*, 807 F.2d 955, 958 (Fed. Cir. 1986). Furthermore, "when determining the patentability of a claimed invention which combines two known elements, the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361,

[11]The plaintiffs submitted, along with their reply brief, a declaration from Dr. Buckberg indicating that the clinical treatment was secret, and therefore not public. However, the court struck that declaration, along with several other pieces of evidence, because they were untimely submitted under the Northern District of Alabama's Uniform Guidelines Regarding Summary Judgment. (*See* Order, dated July 26, 2005, doc. 266.)

1371 (Fed. Cir. 2000). However, one must not "use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.* "[T]he court requires the challenger to show a motivation to combine the references that creates the case of obviousness." *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 727-28 (Fed. Cir. 2002) (brackets omitted).

The defendants base their claim of obviousness on the opinion of Dr. Riggs, on the twelve references cited in his expert reports, on the Dyson/Chapter 22 Reference, and on the Menasche 1982 Reference. With the exception of the Menasche 1982 Reference that the court discussed above, there appears to be no dispute that no single Reference embodies all of the '515 patent's claims.[12] Consequently, the defendants rely on an argument that the prior art reveals a motivation to combine the elements present in the prior art in a way that obviously would lead to the formulation of the Buckberg Solution.

The defendants make this argument with a series of legal obstacles arrayed against them. In addition to the patent possessing a statutory presumption of validity, the finding of the PTO Examiner as expressed in the Reexamination Certificate itself

[12]*See* Holman Decl. (Pla. Ex. VV) ¶¶ 38-64. Furthermore, as the court ruled above, the Menasche 1982 Reference has a calcium concentration that plainly exceeds the range claimed in the '515 patent, and the defendants have produced no clear and convincing evidence that it contains a glucose concentration within the claimed ranges.

is evidence of the invention's lack of obviousness, and the court is obligated to afford the Examiner's conclusion some deference. *See Am. Hoist & Derrick Co.*, 725 F.2d at 1359. Furthermore, the plaintiffs have adduced substantial objective evidence of the invention's nonobviousness. Regarding the invention's commercial success, the defendants not only admit that its success is substantial, but they acknowledge that virtually no substitute products exist: "CAPS has an extremely strong position in the outsourcing of cardioplegia and faces competition from only one or two major companies and a handful of regional providers such as ACS. CAPS has no competitors in the outsourcing of amino acid enriched cardioplegia except ACS, but for ACS, no other substitute product exists." (Defs. Opp. to Pla. 3d Mot. for Summ. J at ¶ (B)(1)).

Moreover, Charles Wall admitted that he copied Dr. Buckberg's solution to formulate ACS' cardioplegia products. (Wall Dep. at 29-30, 48.) Additionally, several prominent cardiovascular surgeons have filed declarations supporting the nonobviousness of the Buckberg Solution in the prior art. Included among these surgeons is Dr. Follette, who authored many of the references relied upon by the defendants to support their claim of obviousness. (*See* Def. Ex. X.)

Thus, to prevail against this evidence, defendants require extremely powerful evidence of a motivation to combine to establish that the Buckberg Solution was

obvious in light of the prior art. Such evidence simply is lacking.[13] Although it is possible to cherry-pick from the prior art the elements that Dr. Buckberg synthesized in the Buckberg Solution, each reference cited by the defendants teaches away from the invention to the same degree that it teach towards it.

The reason for this is that the prior art leading up the Buckberg Solution reveals no discernable trend in the levels disclosed in cardioplegia. For instance, the Menasche 1982, the Menasche 1984, and the Bercot 1979 References all teach hypercalcemia (1250-2500 umol calcium) in cardioplegia. However, other references published during the same period–such as Follette 1978, Follette 1981, the Rosenkrantz 1983, and the Dyson/Chapter 22 References–counsel the opposite, *i.e.*, hypocalcemia. Many references during this period contain no teaching on glucose, *see, e.g.*, Menasche 1984, Irisawa 1983, Follette 1981, Rosenkrantz 1983, Buckberg

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[13]Although the defendants submit the opinion of Dr. Riggs that one can derive a motivation to combine from the prior art, Dr. Riggs's opinion does not prevent the granting of summary judgment because obviousness is a question of law, not one of fact. *See Custom Accessories, Inc.*, 807 F.2d at 958. Thus, Dr. Riggs's opinion, to the extent that it attempts to establish that the Buckberg Solution was obvious in light of the prior art, amounts to an opinion on an ultimate question of law.

Furthermore, Dr. Riggs's opinion is flawed because it attempts to demonstrate a motivation to combine by focusing only on Dr. Buckberg's prior publications, and using the development in Dr. Buckberg's writing to predict what Dr. Buckberg's ideal solution would have been in 1985. This approach is flawed because Dr. Riggs's motivation for focusing exclusively on Dr. Buckberg's writing is his hindsight knowledge that Dr. Buckberg ultimately would synthesize the cardioplegia patented by the '515 patent. The law is clear that using hindsight to retrace the creation of an invention is an improper form of analysis to support a claim of obviousness. *See Beckson Marine, Inc.*, 292 F.3d at 727-28.

1979, and Bercot 1979. Those that do contain teachings on glucose–*e.g.*, Kito 1983, Hashimoto 1984, Follette 1977, and Dyson/Chapter 22–teach hyperglycemia at ranges far in excess of the ranges claimed in the '515 patent.

Reading the prior art references proffered by the defendants, the writing was not on the wall. One could only produce the Buckberg Solution if one had the special insight to know precisely which lines of the prior art to reject and which to accept.[14] As attested to by the nineteen surgeons who provided declarations to support the nonobviousness of Dr. Buckberg's invention during the application for a patent, Dr. Buckberg alone possessed the rare insight necessary to separate the fruitful lines of development from the futile. There is no clear and convincing evidence to the contrary.

Given the mass of objective evidence as to nonobviousness, and in light of the substantial legal presumptions in favor of validity, and the failure of the defendants to demonstrate any expressly stated or inherent motivation to combine the prior art

[14]As discussed above, the Menasche 1982 cardioplegic solution is the one disclosed in the prior art that is most similar to the Buckberg Solution. However, the Menasche 1982 Reference addresses a separate topic. The article lists the formula of the cardioplegic solution only once in a table and it discloses the constituent elements of cardioplegia only briefly and incompletely in the text. The article makes no references of any particular benefits arising from the particular formulation used and it makes no attempt to encourage readers to use a similar solution. The article provides no guidance whatever as to which of the cardioplegia's elements should be pursued and which should be rejected. Consequently, the article fails to provide any motivation to reject its teaching on hypercalcemia, while accepting its teaching as to moderate hyperosmolality and hyperglycemia.

to produce the invention, the plaintiffs are entitled as a matter of law to a judgment that the '515 patent is not invalid for obviousness. Accordingly, the plaintiffs are entitled to summary judgment as to the defendants' claim that the patent is void for obviousness under section 103.

D. *Indefiniteness*

The defendants argue that the '515 patent is void for indefiniteness. A patent is unenforceably indefinite when one skilled in the art would not understand the bounds of the claim when read in light of the specification. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986). If the "claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Id.* An assertion of indefiniteness must be proved by clear and convincing evidence. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990). Close questions of indefiniteness are "properly resolved in favor of the patentee." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1380 (Fed. Cir. 2001).

The defendants argue that the '515 patent is indefinite for two reasons. First, they argue that the phrase "adapted to be diluted" is indefinite. Second, they argue that the word "maintaining," as used in the patent's claims, is indefinite.

The defendants' indefiniteness challenges fail, however, because they lack any

evidentiary support. Critically, all the experts who have offered their opinions in this action have been able to construe the claims of the '515 patent. Furthermore, the defendant, Charles Wall, attests that he understood the claims of the '515 patent well enough to design ACS' products to avoid infringement. Thus, all the evidence supports the conclusion that the claims of the '515 patent are not unenforceably indefinite, and there is no probative evidence to the contrary.

Accordingly, the plaintiffs are entitled to summary judgment on the defendants' affirmative defense and counterclaim that the patent is unenforceably indefinite.

E. ***Conclusion***

The plaintiffs' motion for summary judgment as to the defendants' affirmative defense and counterclaim that the '515 patent is invalid is due to be GRANTED.

III.
Inequitable Conduct

Both parties move for summary judgment on the defendants' claim of inequitable conduct in the procurement of the '515 patent.

A. ***Sufficiency of Defendants' Pleadings***

Federal Rule of Civil Procedure 9(b) states that claims alleging fraud must be pled with particularity. Fed.R.Civ.P. 9(b). Inequitable conduct, while a broader concept than fraud, must also be pled with particularity. *Ferguson Beauregard/Logic*

Controls v. Mega Sys., 350 F.3d 1327, 1344 (Fed. Cir. 2003). Rule 9(b) states that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed.R.Civ.P. 9(b).

"Inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with intent to deceive." *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1373 (Fed. Cir. 2000) (quotation and citation omitted). To satisfy the particularity requirement of Rule 9(b), ACS must plead "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud." *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1380-81 (11th Cir. 1997).[15] Mere conclusory allegations of fraud are insufficient. *Id.* Allegations of inequitable conduct must give CAPS notice of the particular misconduct alleged so that it can defend against the charge. ACS must offer specific facts that CAPS can either deny or controvert. *See Weatherford Int'l, Inc. v. Casetech Int'l, Inc.*, No.

[15]The Federal Circuit applies the law of the regional circuit where the case arises as to procedural issues not unique to patent law, such as those under Rule 9(b). *See Ferguson Beauregard/Logic Controls*, 350 F.3d at 1344.

Civ.A.H.-0305383, 2005 WL 1745457, at *1 (S.D. Tex. July 25, 2005). In holding that inequitable conduct must comply with Rule 9(b), the Federal Circuit has ruled that it would not "infer facts to support a claim that must be pled with particularity." *Ferguson Beauregard/Logic Controls*, 350 F.3d at 1344.

In their Third Amended Answer and Counterclaim, the defendants asserted the following allegations in relation to inequitable conduct:

> **Affirmative Defenses**
>
> . . .
>
> 11. Each claim of the '515 patent is void and unenforceable by virtue of the failure of patentee to advise the Patent Office of prior art which was material to the examination of the application.
>
> . . .
>
> **Counterclaims**
>
> . . .
>
> 9. Upon information and belief, during prosecution of the '515 Patent, the patentee failed to disclose all of the relevant prior art known to it, and thereby failed to satisfy its duty of disclosure to the United States Patent and Trademark Office. Additionally, by manipulation of various measurements and units, the patentee sought to mislead the Patent and Trademark Office regarding the relationship between the claimed invention and the prior art. The '515 Patent is unenforceable as a result of this failure to disclose and/or inequitable conduct during the prosecution of the patent.
>
> . . .
>
> 19. The '515 Patent is invalid and unenforceable.

Third Amended Answer and Counterclaim, Affirmative Defenses, ¶ 11;

Counterclaims, ¶¶ 9, 19.

These allegations fail to state a defense or claim of inequitable conduct with particularity. The allegations do not provide the specific details required by Rule 9(b), such as the precise statements, documents, or misrepresentations made; the time, place, and person responsible for the statement; or the content and manner in which these statements misled the PTO. *See Brooks*, 116 F.3d at 1380-81. The allegations fail to provide CAPS with specific facts to deny or controvert. Instead, the allegations merely restate the elements of an inequitable conduct defense. They are prototypical conclusory allegations.

Accordingly, the defendants have failed to plead an inequitable conduct defense with particularity as required by the Federal Circuit's case law.[16] The

[16]The defendants rely upon *Great American Indemnity Co. v. Brown*, 307 F.2d 307, 308 (5th Cir. 1962), for the proposition that objections under Rule 9(b) are waived if the objections are not presented via a Rule 12 motion. *Great American Indemnity Co.* is distinguishable, however, because it addresses the issue of pleading special damages and arises on an appeal after the entry of judgment. The case does not, and cannot, stand for the proposition that a party waives its 9(b) arguments if it moves for judgment on an inadequately pled defense for the first time at the summary judgment stage.

Furthermore, the court stands by its prior rulings that the defendants failed to show good cause for amending its pleadings to make additional allegations of inequitable conduct after the deadline for amending pleadings had passed.

Lastly, the defendants are mistaken to rely on the court's Order, dated May 5, 2005 (doc. 214), as ruling that the defendants adequately pled a defense of inequitable conduct. That Order merely ruled that defendants' discovery was relevant under Rule 26(b)(1) to allegations made in the defendants' Third Amended Answer and Counterclaim. The Order did not, however, review, analyze, or in any way rule upon the sufficiency of the defendants' allegations of inequitable conduct under Rule 9(b).

plaintiffs are therefore entitled to judgment as a matter of law on the defendants' counterclaims and defenses of inequitable conduct.

B. ***Alternative Ruling on the Merits***

Even if the defendants had adequately pled their claims of inequitable conduct, the court nevertheless would grant the plaintiffs' motion for summary judgment on the claims on their merits.

"Inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with intent to deceive." *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1373 (Fed. Cir. 2000). ACS's unpled claims of inequitable conduct include an assertion that CAPS failed to disclose to the PTO the Dyson/Chapter 22 Reference, and that CAPS misrepresented the data contained in Figure 4 of the patent.

ACS's claim based upon the Dyson/Chapter 22 Reference fails because ACS has adduced no evidence, much less clear and convincing evidence, showing that the Dyson/Chapter 22 Reference was material or that it was omitted with the intent to deceive. First, the Dyson/Chapter 22 Reference discloses no prior art that was not already before the Examiner. Although the Dyson/Chapter 22 Reference discloses a calcium concentration of 150 umol that is within the range claimed by the '515

patent, the Follette 1978 Reference does so as well. Furthermore, the Dyson/Chapter 22 Reference teaches a glucose concentration (approximately 2160 mg%) that far exceeds the concentration of the '515 patent, although it mirrors glucose concentrations disclosed in the prior art references that were before the patent examiner, such as the Kito 1983, Hashimoto 1984, and Follette 1977 References. Thus, the Dyson/Chapter 22 Reference is merely cumulative and not material. *See Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1574-75 (Fed. Cir. 1997) (no inequitable conduct where the uncited reference teaches no more than what a reasonable Examiner would consider to be taught by the prior art already before the PTO).

Second, ACS presents no evidence that Dr. Buckberg intentionally withheld the references to deceive the Examiner as to the state of the prior art. The only evidence of Dr. Buckberg's intent indicates that the materials were omitted for innocent reasons, *i.e.*, because the subject of the Dyson/Chapter 22 Reference was not the formula of the cardioplegia, but rather was the delivery system used to administer the cardioplegia. (*See* Buckberg Decl., Pla. Ex. WW, ¶ 22; Holman Decl., Pla. Ex. VV, ¶ 56.)

Because there is no evidence of either materiality or intent to deceive, the plaintiffs are entitled to judgment as to the defendants' unpled defense and

counterclaim of inequitable conduct based upon the Dyson/Chapter 22 Reference.

The defendants' second basis for their inequitable conduct claim is Figure 4 of the '515 patent. The defendants allege that Figure 4 purports to record the results of the use of a cardioplegic solution with an osmolarity of 400-500, when in reality the solution had a osmolarity of 360-380 mOsmol.[17] This claim fails, however, because the defendants present no evidence, other than attorney speculation, that Figure 4 misstates anything, nor have defendants produced any evidence to indicate that, if a misstatement was present, it was made intentionally. To the contrary, it is undisputed that the article upon which the defendants rely to show that Figure 4 is incorrect was submitted to the Examiner. (*See* Def. Ex. P.) This is strong evidence that Dr. Buckberg did not intend to deceive the Examiner and the defendants have failed to rebut it. Accordingly, the plaintiffs are entitled to summary judgment as to the defendants' counterclaim and defense of inequitable conduct based upon the alleged misrepresentation contained in Figure 4.

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[17]Defendants base their argument of misrepresentation on the assertions (1) that the research leading to the '515 patent is the same as the research reported in Article IX of the Journal of Thoracic and Cardiovascular Surgery, and (2) that Article IX reports the data differently from how the data is reported in the '515 patent. (*See* Def. Ex. Z (Bradley S. Allen, M.D., *et al.*, *Studies of Controlled Reperfusion After Ischemia: IX. Reperfusate Composition: Benefits of Marked Hypocalcemia and diltiazem on Regional Recovery*, J. OF THORAC. CARDIOVASC SURG. v. 92, at 564-572 (1986))). Apparently making them for the first time in their summary judgment briefs, defendants fail to present any evidence to support either assertion.

C. *Conclusion*

The plaintiffs' motion for summary judgment as to the defendants' counterclaim and affirmative defense of inequitable conduct is due to be **GRANTED**.

IV.
Validity of the Certificate of Correction

Along with their motion on inequitable conduct, the defendants argue that the certificate of correction is invalid. The defendants base their argument on *Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F.3d 1358, 1375 (Fed. Cir. 2001), which holds that a certificate of correction that corrects "mistakes of minor character" may not correct a mistake that broadens a patent's claims. Because the court already has held that the certificate of correction issued on the '515 patent corrected "a mistake of minor character," (Order, dated May 2, 2002, doc. 64, at 1), the defendants argue that the certificate is invalid because the certificate accomplished a broadening of the scope of the patent. Furthermore, the defendants submit additional evidence that they argue demonstrates that the COC expanded the claims of the '515 patent. However, the court already has ruled that "the defendants may present the question of the COC's validity to the jury." (*Id.*)

To the extent that the defendants' argument constitutes a request for the court to revisit this ruling, the court declines the request. The defendants' evidence tends

to show that osmolarity and osmolality are not identical measures. (*See*, *e.g.*, Riggs Decl. (doc. 239, Defs. Ex. 2).) However, there continues to be a question of fact as to whether "an increased level of between about 400-500 mOsmol/kg" is broader than "an increased level of between about 400-500 mOsmol/L." Accordingly, the defendants' motion for summary judgment on the validity of the certificate of correction is due to be **DENIED**.

V.
Infringement

The defendants move for summary judgment on the plaintiffs' claims of infringement prior to the issuance of the certificate of correction ("COC"). The plaintiffs move for summary judgment on the claims of infringement after the issuance of the COC. Each motion is addressed in turn.

A. *Legal Standard*

Evaluating claims of infringement involves two steps, "(1) claim construction to determine the scope and meaning of the claims asserted to be infringed, followed by (2) a determination of whether the properly construed claim encompasses the accused [device or] method." *See Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 189 F.3d 1370, 1373 (Fed. Cir. 1999). Because the plaintiffs' claims of infringement are before the court on summary judgment, the summary judgment standard laid out

above applies.

B. *Claim Construction*

The '515 patent has three independent claims: claims 1, 7, and 13. Each independent claim describes treatment for the human heart for the purpose of preventing and reversing muscle damage due to ischemia. Claim 1 describes the patented treatment as "an amino acid enriched cardioplegic solution for use in treating human hearts"; whereas claim 7 describes the treatment more generically as "a method for treating human hearts"; while claim 13 describes the treatment as "[a] composition of matter for introduction into human hearts". All three independent claims require: (1) a calcium concentration of "between about 50-300 umol," (2) a metabolizable substrate concentration of "between about 400-1000 mg%," and (3) an osmolality or osmolarity of "between about 400-500 mOsmol." '515 patent at 8-10.

Following the *Markman* hearing, the court issued orders on May 2, 2002, and again on September 4, 2003,construing the scope and meaning of the claim contained in the '515 patent. In the September 2003 Order, the court determined that the word "about" was to be given "its common sense meaning as a term of approximation, including numbers both below and above the ranges specified in the '515 patent." *Markman* Order, dated Sept. 4, 2003. The court further ruled that the limitation "between about 400-500" encompasses "a range of osmolarity or osmolality from

385-515." *Id.*[18]

1. Application of the COC

The defendants move for summary judgment on the plaintiffs' claims of infringement of the patent prior to the issuance of COC. The defendants make this motion in the alternative. Their primary position is that the COC does not apply to this suit because the suit was filed prior to the issuance of the COC. The defendants advance the instant motion for summary judgment only if the court rejects that argument and rules that the COC applies to this action as well as to all causes of action that accrued after the issuance of the COC. Accordingly, it would be premature for the court to rule on the defendants' instant motion without first determining the threshold question of whether the COC applies to this suit at all. Because the issue has been fully briefed by the parties, and because the resolution of this issue is necessary to determine the infringement questions pending before the

[18]Although the court issued its construction of the patent's claims in its Orders of May 2, 2002, and September 4, 2003, the defendants now urge the court to amend its construction by construing the term "maintaining" as used in the '515 patent's claims 7 through 12. The defendants assert that the court should construe the term "maintaining" to mean that the '515 patent is not infringed unless a solution is within the claimed ranges throughout the treatment being administered to a patient. The defendants make this argument too late as the court already has issued its claim construction of the '515 patent. In the interest of finality, the issue of construction shall not be revisited or endlessly litigated. In addition, even if the asserted construction of the term "maintaining" were considered, the court would reject it. It is undisputed that it is impossible to measure the levels of cardioplegic solutions after they have been administered to the patient. Thus, adopting the defendants' proposed construction would render the '515 patent uninfringeable due to the impossibility of measuring infringement. There is no merit to a claim construction that yields such an absurd result.

court, the court will address whether the COC applies to this action.

The parties agree that the Federal Circuit's opinion in *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000), provides the definitive authority as to the application of the COC. However, the parties quarrel over the meaning and effect of the Federal Circuit's holding in that case. At issue is whether the Federal Circuit held that a COC applies only to *causes of action* arising after the issuance of the COC or whether the COC applies only to *lawsuits* filed after the COC's issuance. The confusion as to how to interpret the Federal Circuit's opinion arises from the fact that the *Southwest* opinion uses the terms "lawsuit" and "cause of action" interchangeably throughout the opinion. Thus, the defendants quote the passages in *Southwest Software* containing the phrase "lawsuit," *see, e.g., id.* at 1294 ("We hold that the certificate of correction that added the Program Printout Appendix is not to be given effect in this pre-certificate lawsuit."), while CAPS cites to the sentences where the phrase "cause of action" is used. *See, e.g., id.* at 1294 ("The certificate of correction is only effective for causes of action arising after it was issued.").

The plaintiffs observe that the reason the Federal Circuit could use the terms "cause of action" and "lawsuit" interchangeably in *Southwest Software* is that, under the particular facts of that case, the terms had the same effect. The defendant in *Southwest Software* ceased its allegedly infringing activity upon the filing of the

lawsuit. *See id.* at 1287. Because the relevant certificate of correction in that case issued while the suit was pending, the plaintiff's lawsuit was filed, and all of the plaintiff's causes of action arose, prior to the COC's issuance. In contrast to the instant action, the Federal Circuit in *Southwest Software* did not confront a situation where some of the plaintiffs' causes of action arose prior to the issuance of the COC and some arose after its issuance. Because of these particular facts, *Southwest Software* must be interpreted with care.

Pursuant to such a careful reading, the court finds that the *Southwest Software* opinion supports the interpretation that a COC applies to *causes of action* arising after the COC's issuance, even if the lawsuit is filed prior to the COC's issuance. The Federal Circuit explained its holding as motivated, in part, by the court's desire to avoid the "illogical and unworkable result" that a patent holder might be able "to sue an alleged infringer for activities that occurred before the issuance of the certificate of correction" where the patent appeared invalid prior to the issuance of the COC but was rendered valid as a result of the COC. In such a case, the Federal Circuit opined that, prior to the issuance of the certificate, "reasonable competitors would be justified" in competing with the invention. *See id.* at 1295 - 1296.

This portion of the Federal Circuit's discussion is dispositive because the Federal Circuit's "illogical and unworkable result" would not be avoided if a COC

applied to lawsuits filed after the issuance of a COC where the lawsuit sought to recover on causes of action accruing prior to the issuance of the COC. The only interpretation that avoids the result decried by the Federal Circuit is the interpretation that a COC applies only to causes of action arising after the issuance of the COC, regardless of when the lawsuit seeking to recover on those causes of action is filed.

Also supporting this interpretation of the *Southwest Software* opinion is the Federal Circuit's following caveat: "Finally, we point out that, for any cause of action arising after April 1, 1997, the date the certificate of correction issued, the certificate will be treated as part of the original patent. Therefore, any invalidity arising from the absence of the Program Printout Appendix only affects causes of action arising before the certificate issued. Put another way, if claim 1 is found to have been invalid without the Program Printout Appendix, the invalidity ceased on April 1, 1997, when the PTO issued the certificate of correction." *Id.* at 1297. This caveat simply is incompatible with the defendants' interpretation that a COC applies only to lawsuits filed after its issuance. Were the defendants' interpretation correct, the caveat would have no application since the lawsuit in *Southwest Software* obviously had commenced prior to the COC's issuance. The only interpretation that gives this dictum meaning is that the Federal Circuit was advising the district court that the plaintiff could proceed on any claims arising after the COC's issuance.

Honoring that instruction, this court will permit the plaintiffs here to do the same. For any causes of action for infringement of the '515 patent accruing after the issuance of the certificate of correction, the COC shall apply, provided, of course, that the certificate ultimately is held valid. For causes of action accruing prior to the issuance of the COC, the COC shall have no application.

C. *Facts*

In support of the claims of infringement, the plaintiffs present evidence from two experts. The first expert is Dr. Stanley B. Digerness. Dr. Digerness tested fourteen samples of the defendants' products that defendants provided during discovery. The defendants admit that they commercially produce solutions 1-12.

Dr. Digerness obtained blood samples from the cardiopulmonary bypass reservoir of five randomly selected patients. Dr. Holman provided an additional sample. After diluting each of the defendants' 14 sample crystalloid solutions with the collection blood samples, Dr. Digerness measured the calcium ion concentrations, metabolizable substrate concentration, osmolality, and pH of each sample.

Dr. Digerness found that, when mixed 1 to 4 with blood, all fourteen of the defendants' samples had calcium concentrations ranging from 90-199 umol; glucose concentrations ranging from 639-934 mg%; and amino acid concentrations ranging from 24.2 to 26.5 mmol/L, in an even proportion between glutamate and aspartate.

Dr. Digerness also found that samples 1, 7, 9, 11, 12, 13, and 14 had a pH ranging from 7.353 to 7.603.

Dr. Digerness found that samples 1, 7, 9, 11, 12, 13, and 14 had osmolalities ranging from 368 to 442 mOsmol/kg, with twenty-two of the forty-six data points at 385 mOsmol/kg or greater. Sample 1 had osmolalities of 385, 391, and 398 when mixed with blood from patients 3, 1, and 2, respectively; and 394 when mixed with Dr. Holman's blood sample. Sample 7 had an osmolality of 385 and 393 when mixed with blood from patients 3 and 2, respectively. Sample 9 had an osmolality of 389 and 390 when mixed with blood from patients 2 and 4, respectively. Samples 11 and 12 had osmolalities of 392 when mixed with blood from patient 2. Sample 13 had an osmolality of 388 when mixed with blood from patient 2. Sample 14 had an osmolality of 386 when mixed with blood from patient 2. When mixed with the blood of the other patients, however, these samples had osmolalities of less than 385. Furthermore, Dr. Digerness found that samples 2, 3, 4, 5, 6, 8, and 10 had osmolalities of less than 385 mOsmol/kg.

The plaintiffs' second expert is Dr. Hal Peterson. Dr. Peterson did not test solutions prepared by ACS. Instead, Dr. Peterson tested two solutions prepared by the plaintiff CAPS (CS-1 and CS-2) that Dr. Peterson attests is "chemically identical" to solutions sold by ACS to the University Hospital of New Orleans and Riverview

Hospital. Dr. Peterson found that, when mixed with human blood in a 1:4 ratio, these samples, CS-1 and CS-2, had osmolalities ranging from 392 to 443 mOsmol/kg. Dr. Peterson attests that CS-1 and CS-2 are "chemically identical" to defendants' sample solutions 11 and 12.

The defendants present evidence from their expert, Dr. David R. Wade. Using the test results produced by Dr. Digerness, Dr. Wade calculated the osmolarity of the 14 cardioplegic solutions tested by the plaintiffs' experts. Dr. Wade calculated that each of the fourteen solutions had osmolarities of between 349 and 377 mOsmol/L.

D. ***Infringement Prior to the Issuance of the COC***

Prior to the issuance of the COC on January 30, 2001, the '515 patent covered cardioplegic solutions with osmolarities of about 400-500 mOsmol/L. The court has interpreted the claim of between about 400-500 mOsmol/L to apply to all solutions having osmolarities within the range of 385-515 mOsmol/L. The testimony of Dr. Wade is undisputed that none of the defendants' 14 tested solutions came within the claims range of 385-515 mOsmol/L. Osmolarity is a necessary element of the '515 patent under all three of its independent claims. Consequently, there is no evidence of direct infringement of the patent as it read prior to the issuance of the COC.

The plaintiffs argue that questions of fact exist regarding whether the

defendants nevertheless are liable for infringement under the doctrine of equivalents. Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claims may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused patented invention." *Warner Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997).

The defendants argue that plaintiffs are barred from invoking the doctrine of equivalents due to prosecution history estoppel. It is true that prosecution history estoppel, if applicable, would prevent the plaintiffs from taking advantage of the doctrine of equivalents.[19] However, there is no question that amendment-based prosecution history estoppel requires, at minimum, that the patentee have made a narrowing amendment to his or her claims during the patent review process. *See Abbott Labs. v. Dey, L.P.*, 287 F.3d at 1103 ("[T]here can be no amendment-based estoppel with respect to this claim limitation [that was not amended during the prosecution of the patent]."). Rather, the only amendment that the defendants can point to is the addition of the language "at an increased level" in claims 1 through 6. Thus, the defendants can make no argument that the doctrine of equivalents does not

[19]Prosecution history estoppel can be amendment-based or it can be argument-based. *See Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1103 (Fed. Cir. 2002). Here, all of defendants' prosecution history estoppel arguments are amendment-based.

apply to claims 7 through 17[20].

In addition, the language that the defendants rely upon in no way limits the scope of claims 1 through 6. The defendants argue that the language "at an increased level" means that the doctrine of equivalents can only be applied to levels higher than the patent's claimed ranges of 400-500 mOsmol, but may not be applied to anything below that range. The court ascribes no such meaning to this phrase. Instead, the court interprets "at an increased level" to indicate merely that the cardioplegic solution must be hyperosmolar as compared to the normal osmolarities found in human blood. As human blood normally has an osmolarity of between 280 and 300 mOsmol, the '515 patent's requirement that the solution be hyperosmolar cannot be interpreted to limit the patent only to ranges above 400 mOsmol.

Indeed, the court rejected this very argument by the defendants during the claim construction phase of this action. At that time, the defendants argued that the language "at an increased level" required the court to limit the claimed range of between about 400 to 500 mOsmol as covering only ranges above, but nothing below, 400 mOsmol. The court rejected that argument and ruled that the patent's claim of "about 400-500 mOsmol" included "numbers both below and above the ranges

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[20] The defendants, in their briefs, argue for amendment-based estoppel only. That is, they do not argue that argument-based prosecution history estoppel applies. See, doc. 235 at pp. 26-23.

specified in the '515 patent." (*Markmen* Order, dated Sept. 4, 2003.) Accordingly, prosecution history estoppel is not applicable here, and the plaintiffs are not barred from arguing for the application of the doctrine of equivalents.

The essential inquiry under the doctrine is, "Does the accused or process contain elements identical or equivalent to each claimed element of the patented invention?" *Warner Jenkinson Co.*, 520 U.S. at 40. This analysis may be determined under the "triple identity" test–which focuses on the "*function* served by a particular claim element, the *way* that element serves that function, and the *result* thus obtained by that element–or it may be evaluated by inquiring whether the allegedly infringing device or process possess only 'insubstantial differences.'" *Id.* (emphases added). In *Warner Jenkinson Co.*, the Supreme Court observed that the triple identity test is better suited for mechanical devices than for other products or processes. Thus, the more suitable framework here is to inquire whether the defendants' products contain only "insubstantial differences" from the plaintiffs' products. Under either framework, "[t]he determination of equivalence should be applied as an objective inquiry on an element-by-element basis." *Id.* "[E]quivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co. (Graver II)*, 339 U.S. 605, 609 (1950).

"A finding of equivalence is a determination of fact." *Graver Tanks & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 65, 609 (1950). "[E]quivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case." *Johnson & Johnson Assocs. Inc. v. R.E. Serv. Co. Inc.*, 285 F.3d 1046, 1053 (Fed. Cir. 2002).

The facts before the Supreme Court in *Warner Jenkinson Co.* are similar to those here. There, the patent at issue covered an ultrafiltration process that operated at a "pH from approximately 6.0 to 9.0." *See Warner Jenkinson Co.*, 520 U.S. at 22. The alleged infringer used an ultrafiltration process having a pH of 5.0. *Id.* The Supreme Court held in that case that, as long as prosecution history estoppel did not apply, the doctrine of equivalents could be applied. Based upon this holding and the Supreme Court's view that a jury reasonably could find a pH of 5.0 equivalent to a pH of 6.0-9.0, the court sees no reason why an osmolarity of between 349 and 377 mOsmol/L might not be considered equivalent to an osmolarity of between 385 and 515 mOsmol/L.

Furthermore, although the Supreme Court ruled that intent is irrelevant to the application of the doctrine of equivalents, the plaintiffs have submitted evidence that the defendants developed their solutions by copying the plaintiffs' solutions precisely except that they lowered the osmolarity of the solutions to just under the ranges

claimed by the '515 patent. (*See* Memo of Charles Wall, dated June 2, 1998, Pla. Ex. L; Letter by Robert Veal, dated Aug. 14, 1998, Pla. Ex. G.) This evidence is sufficient to invoke the doctrine of equivalents, which is designed to ensnare exactly "the unscrupulous copyist [who] make[s] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law." *Graver Tanks & Mfg.*, 339 U.S. at 605. If a jury determined that, as a factual matter, an osmolarity of 349-377 mOsmol/L constitutes an insubstantial difference from an osmolarity of 385-515 mOsmol/L, the jury reasonably could find that the defendants infringed the '515 patent as it read prior to the issuance of the COC.

In response, the defendants have submitted the statements of Charles Wall, who asserts that Buckberg misread the prior art by failing to appreciate that the optimal osmolarity for cardioplegia is significantly below the '515 patent's claimed ranges of 400-500 mOsmol/L. (*See* Wall Decl. ¶ 9.) Based upon this assertion, Wall claims that the alterations of his solutions are not equivalents but instead constitute substantial improvements on the cardioplegia. (*Id.*)

This conflicting evidence creates a question of fact to be resolved at trial. Therefore, because prosecution history estoppel cannot apply in this case, the plaintiffs may proceed on their infringement claims based upon the '515 patent as it

read prior to the issuance of the COC. Even though the defendants' solutions did not literally infringe the '515 patent prior to the issuance of the COC, the plaintiffs may adduce proof that the osmolarity of the defendants' solutions of between 349 to 377 mOsmol/L is equivalent to the claimed range of between 385 and 515 mOsmol/L. Accordingly, the defendants' motion for summary judgment on the plaintiffs' claims of infringement of the patent as it read prior to the issuance of the COC are due to be, and hereby are, **DENIED.**[21]

E. ***Infringement Following the Issuance of the COC***

The plaintiffs have moved for summary judgment on their claims of infringement of the '515 patent as amended by the COC. The tests performed by Drs. Holman and Digerness indicate that the defendants' solutions 1, 7, 9, 11, 12, 13, and 14 come within the claimed ranges of the patent as to every element.

Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had a calcium concentration between 90-199 umol. This is within the '515 patent's claimed range of 50-300 umol, and the defendants have presented no evidence to the contrary. Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had a glucose concentration of between 639 and 934 mg%. This is within the '515 patent's claimed

[21]Because summary judgment as to infringement is denied, it necessarily follows that the plaintiffs' motion for summary judgment as to whether the infringement was willful also is **DENIED**.

range of 400-1000 mg%, and the defendants have presented no evidence to the contrary. Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had an amino acid concentration of between 24.2 and 26.5 mmol/L in even proportions of glutamate and aspartate. This is within the '515 patent's claimed range 10-30 mmol/L of aspartate and between 10-30 mmol/L of glutamate, and the defendants have presented no evidence to the contrary. Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had a pH of between 7.353 and 7.603. This comes within the claimed pH range of 7.5 and 7.7 pH, and the defendants have presented no evidence to the contrary. Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had an osmolality of between 385 and 398 mOsmol/kg. This is within the '515 patent's claimed range 385 to 515 mOsmol/kg, and the defendants have presented no evidence to the contrary.

Thus, the undisputed evidence shows that the defendants directly infringe the '515 patent as to claims 13 through 17. As to these claims, the defendants' infringement is direct because the defendants manufacture and sell crystalloid cardioplegic solutions which are adapted to be diluted with blood at a 1 to 4 ratio. (*See* '515 patent claims 13-17; Holman Decl. at ¶ 2.) With respect to claims 1 through 12 and 18, the defendants' infringement is contributory because they sell their cardioplegia products with the intent that the customers will mix them with

blood at a 1 to 4 ratio, thereby bringing the solution within the scope of '515 patent's claims.[22]

The undisputed evidence shows, therefore, that the defendants are liable for direct and contributory infringement of the '515 patent as amended by the COC. However, because the court already has ruled that the defendants may present evidence at trial challenging the validity of the COC, the court cannot grant summary judgment on infringement at this time. Instead, the Court will grant summary judgment to the plaintiffs only in part and deny it in part. The plaintiffs' motion for summary judgment is **GRANTED IN PART** as to the issue of whether the defendants are liable for infringement of the '515 patent as amended by the COC, provided that the COC is valid. The motion is **DENIED IN PART** insofar as the validity of the COC is a question of fact to be determined at trial.

Similarly, the court will grant in part and deny in part the plaintiffs' motion for summary judgment on their claim that the defendants willfully infringed the '515 patent. The plaintiffs claim that the defendants' infringement of the patent was

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[22]To be contributorily liable for infringement, it must be shown that (1) the defendants sold solutions comprising a material part of the patented invention; (2) the defendants knew the solutions sold were especially made for use in practicing the patented invention; and (3) the solutions sold were not a staple article or commodity of commerce suitable for substantial noninfringing use. *See* 35 U.S.C.A. § 271(c). Here, the memorandum written by Charles Wall, dated June 2, 1998 (Pla. Ex. L), shows that the defendants intended their customers to mix ACS's solutions with blood at a 1 to 4 ratio, which would produce cardioplegic solutions used for the treatment of human hearts within the claimed ranges of the '515 patent.

willful and seek to recover the treble damages authorized by statute for willful infringement. *See* 35 U.S.C.A. § 284.

The undisputed evidence indicates that the defendants directly copied the plaintiffs' patented solutions in developing their products. (Wall Dep. at 29-30, 48; Memo of Charles Wall, dated June 2, 1998.) This is strong evidence of willful infringement. *See Stryker Corp. v. Intermedics Orthopedics, Inc.*, 96 F.3d 1409, 1414 (Fed. Cir. 1996). The only evidence rebutting a finding of willfulness is the opinion letter that the defendants obtained from their counsel, Robert Veal. Ordinarily, an opinion letter from counsel will insulate an infringer from a charge of willful infringement if the opinion of counsel is both favorable and competent. *See Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1363 (Fed. Cir. 1998).

Here, however, defendants' counsel, Robert Veal, advised the defendants only as to the '515 patent as it read prior to the issuance of the COC.[23] The defendants have submitted no evidence that they obtained a competent opinion from counsel that

[23]In his opinion letter, Veal advised the defendants to keep the ranges of the constituent elements of their solutions "significantly out of the specified ranges" of the '515 patent. Veal opined that an osmolarity of 360 mOsmol/L would qualify as significantly outside of the '515 patent's claimed range. The plaintiffs argue that the defendants failed to adhere to Veal's advice because the undisputed evidence here indicates that the defendants' products contained osmolarities of as high as 377 mOsmol/L. Because the court denied summary judgment on the plaintiffs' claims of infringement prior to the issuance of the COC, the court does not need to resolve at this time whether Veal's letter constitutes a defense to willful infringement of the '515 patent prior to the issuance of the COC.

would insulate them from liability for infringement of the corrected patent. Accordingly, there is no dispute of fact as to the willfulness of the defendants' infringement of the '515 patent following the issuance of the COC. The court therefore will, and hereby does, **GRANT IN PART** summary judgment as to the willfulness of the defendants' infringement of the '515 patent following the issuance of the COC, provided that at trial the COC is found to be valid. The plaintiffs' motion for summary judgment on its claim that the defendants' infringement of the patent was willful is in all other respects **DENIED**.

VI.
Counterclaims

The plaintiffs move for summary judgment on the defendants' counterclaims of (1) false marking under the False Marking Statute, 35 U.S.C. § 292(a) ("Section 292") and (2) false advertising under the Lanham Act, 15 U.S.C. § 1125 (a)(1)(B). Each motion is addressed in turn.

A. *Facts*

In support of the counterclaims of false marking and false advertising, the defendants offer expert reports from Dr. Stanley B. Digerness and Dr. Hal Peterson. These expert reports are discussed at length *supra*. The defendants rely specifically on the results in each report for the osmolalities of samples of the Buckberg Solution

tested. As described above, the Buckberg Solution consists of an amino acid enriched cardioplegic solution having (1) a calcium ion concentration of between 50-300 umol; (2) a concentration of metabolizable substrate between about 400-1000 mg%; and (3) an osmolality of between about 400-500 mOsmol.[24] It is not disputed that the plaintiffs mark all amino enriched cardioplegic solutions as being covered by the '515 patent.

B. ***False Marking***

Count II of the defendants' counterclaim alleges false marking under Section 292. Section 292 is a private attorney general statute that allows recovery of penal damages against anyone who fraudulently misrepresents that a product is subject to a patent. The damages awarded under Section 292 are shared equally with the government. See 35 U.S.C. § 292(b).

The threshold for establishing a successful Section 292 claim is extremely high. *Brose v. Sears, Roebuck, & Co.*, 455 F.2d 763, 768 (5th Cir. 1972).[25] Both the language of Section 292 and the binding authority in this Circuit place on the defendants the burden to plead and produce facts demonstrating that the plaintiffs, in

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[24]In the *Markman* Order dated May 2, 2002, the court ruled that an osmolality of "between about 400-500 mOsmol" encompasses osmolalities "from 385-515."

[25]The Eleventh Circuit, in *Bonner v. City of Prichard*, 661 F.2d 1206, 1207 (11th Cir. 1981) (en banc), adopted as precedent decisions of the former Fifth Circuit rendered prior to October 1, 1981.

marking the solution with the '515 patent, had the specific intent to deceive the public into believing something that the plaintiffs knew to be false. *Id*. See also *Clontech Laboratories, Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1355 (Fed. Cir. 2005) (intent is a key element under a Section 292 claim); *Arcadia Machine & Tool, Inc. v. Sturm*, 786 F.2d 1124, 1125 (Fed. Cir. 1986) (mismarking must have been done for the purpose of deceiving the public); *Mayview Corp. v. Rodstein*, 620 F.2d 1347, 1359 (9th Cir. 1980) (same). In order to demonstrate an intent to deceive, the defendants must show by a preponderance of the evidence that the plaintiffs "did not have an honest good faith belief in marking its products." *Clontech Laboratories, Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1355 (Fed. Cir. 2005) (citing *Brose v. Sears, Roebuck, & Co.*, 455 F.2d 763, 768-769 (5th Cir. 1972)).

The sole issue for this court to consider in analyzing the counterclaim for false marking is whether or not the defendants have established, through a preponderance of the evidence, that the plaintiffs manifested the intent to deceive when marking the cardioplegic solutions that tested outside the acceptable osmolality range for the '515 patent. Because the court finds that the defendants fail to meet its burden of offering evidence that demonstrates an intent to deceive on the part of the plaintiffs, the Section 292 claim fails.

The Eleventh Circuit has "adopted the formulation that an honest, though

mistaken, mismarking of an article would not trigger liability under [Section 292]." *Clontech Laboratories, Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1352 (Fed. Cir. 2005) (citing *Brose v. Sears, Roebuck and Co.*, 455 F.2d 763, 768-769 (5th Cir. 1972)). Section 292 is not a statute of strict liability for mismarking. *Id*. "Intent to deceive is a state of mind arising when a party acts with sufficient knowledge that what it is saying is not so and consequently that the recipient of its saying will be misled into thinking that the statement is true." *Clontech* 406 F.3d 1347 at 1352 (citing *Seven Cases v. United States*, 239 U.S. 510, 517-517, 36 S.Ct. 190, 60 L.Ed. 411 (1916)).

Intent to deceive is proved when (1) the patent does not cover the marked article; and (2) the differences between the mismarked article and a properly marked article are "so plain that no one in good faith" could think otherwise.[26] *Brose v. Sears, Roebuck and Co.*, 455 F.2d 763, 768 (5th Cir. 1972).

> We can assume that if a device claimed to be covered by license of a cited patent is so obviously not revealed by it as the patentese world would view it, the use of such a legend would be mismarking. But where the device is within the specific field covered by the patent and uses materials and methods similar to the technical patent disclosures,

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[26]Claims brought under Section 292 as part of a strategic plan in pending patent litigation are not favored. See *Brose v. Sears, Roebuck and Co.*, 455 F.2d 763, 768 (5th Cir. 1972) ("It is at this point that the law-perhaps out of distaste for blood money suits-compels a positive showing. For here not only are objective physical facts involved. Here are questions of motive, purpose and attitudes.").

> the licensee's use in good faith reliance on the license is not to be transmuted into an evil purpose to deceive the public merely on proof and finding that for one or more or all of the reasons skilled patent advocates could think up, the embodiment in question does "not read on" or is not an "infringement" of the cited patent. But this presupposes that the private attorney general has established that the device is not within the patent. Only at that time does the good faith purpose or motive of the marker of a license to a cited patent come into question.

Id. at 768-769. The defendants fail to meet their burden of proof under the first element of the intent test in *Brose*; therefore the court need not consider the merits of the present case under the second element of the test.

It is undisputed that the plaintiffs mark all their amino enriched cardioplegic solutions with the '515 patent and that the acceptable osmolality range covered under the patent is between 385-515 mOsmol.

The defendants claim that they need not test the plaintiffs' marked solutions to determine that the solutions fall outside the range of the '515 patent because the plaintiffs' own tests demonstrate that fact. See *Defendants' Memorandum in Opposition to Plaintiffs' MSJ No. 3 False Marking and False Advertising* at 16. The defendants do not challenge that the Buckberg Solution marked by the plaintiffs contains a calcium ion concentration of between 50-300 umol and a concentration of metabolizable substrate between 400-1000 mg% as is required under the patent; rather, the defendants solely posit that certain marked containers of solution fall

outside the '515 patent osmolality range of "about 400-500 mOsmol." An examination of the evidence is contrary to the defendants' position. None of the plaintiffs' tests show an osmolality range of the plaintiffs' amino enriched cardioplegic solution outside the patent range of "about 400-500 mOsmol."

The bulk of the defendants' argument and evidence that the plaintiffs' marked solutions fall outside of the '515 patent concern the osmolarity of the plaintiffs' marked solution. As arguments related to the osmolarity of the plaintiffs' solution have been expressly rejected by this court they will not be considered.[27]

The defendants have not satisfied their burden under the first element of the test in *Brose*. In addition, the court notes that the defendants' counterclaim fails under the second element of a *Brose* analysis. The differences between a mismarked solution falling outside of the osmolality range of the '515 patent and a properly marked solution are so negligible that no one in good faith could find that the plain differences between the two solutions reveal an intent to deceive on the part of the plaintiffs. A variation in the osmolality range of a marked solution coupled with the lack of evidence establishing that the plaintiffs' marked solution does not contain a calcium ion concentration of between 50-300 umol or that the marked solution does

[27]As previously discussed, the court's *Markman* Order dated May 2, 2002, held that claims involving the '515 patent must be analyzed using the term "osmolality" and not "osmolarity."

not contain a concentration of metabolizable substrate between 400-1000 mg% as is required under the patent leads the court to hold that, even if there is a variation in the osmolality range of the marked solution outside of the '515 patent parameters, such a variation does not rise to the level of an intent to deceive under the second element of the test in *Brose*. Accordingly, the plaintiffs' motion for summary judgment on the defendants' claim of false marking is due to be, and hereby is, **GRANTED**.

C. False Advertising

Count III of the defendants' counterclaim alleges that the plaintiffs' marking of its amino acid enriched solutions with the '515 patent comprises false advertising actionable under the Lanham Act.

"It is well-settled that no proof of intent or willfulness is required to establish a violation of the Lanham Act ... for false advertising." *Vector Products, Inc. v. Hartford Fire Ins. Co.*, 397 F.3d 1316, 1319 (11th Cir. 2005). To succeed on a false advertising claim under the Lanham Act, a defendant must show that: (1) the plaintiff made false or misleading statements about its product in an advertisement; (2) the advertisement actually deceived, or had the tendency to deceive, the targeted audience; (3) the deception is material; (4) the plaintiffs' advertised product traveled in interstate commerce; and (5) the defendant has been or is likely to be injured as a result of the false or misleading advertisements." See *Hyman v. Nationwide Mut. Fire*

Ins. Co., 304 F.3d 1179, 1196 (11th Cir. 2002). The failure of the defendants to satisfy their burden with respect to any one of the foregoing elements warrants summary judgment in favor of the plaintiffs. See *Laughlin Products, Inc. v. ETS, Inc.*, 257 F. Supp. 2d 863 (N.D. Tex. 2002) (the plaintiffs need "only show that [defendants] who bear the burden to prove, have adduced no evidence to support an essential element of the case.").

The defendants have not offered any facts and this court cannot locate any evidence in the record showing that: (1) the plaintiffs marked its amino enriched cardioplegic solutions as being patented; (2) the marking of the plaintiffs' solutions actually deceived or had the tendency to deceive the public; or (3) that any alleged deceptive marking would be material in that the marking somehow influenced customers' purchasing decisions. The parties concede that the marked solutions are sold and transported as a part of interstate commerce. Because the first three elements of the test articulated in *Hyman* are not satisfied, the court will not provide analysis under the moot fifth element as to whether or not the defendants have suffered an injury as a result of hypothetical false advertising on the part of the plaintiffs.[28] Accordingly, the plaintiffs' motion for summary judgment on the

[28]The plaintiffs and defendants reference the court to *Zenith Elect. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1348 (Fed. Cir. 1999), in order to add an additional element for analysis to the defendants' Lanham Act claim for false advertising that the plaintiffs' alleged marketplace

defendants' claim of false advertising under the Lanham Act is due to be, and hereby is, **GRANTED**.

This opinion shall be carried out by a separate Order.

DONE and **ORDERED** this 10th day of January, 2006.

VIRGINIA EMERSON HOPKINS
United States District Judge

activity in support of the '515 patent "must have been undertaken in bad faith." As neither party cited to Eleventh Circuit or U.S. Supreme Court precedent on this issue and the court, through its own examination, has not located a binding decision relating to the element of "bad faith" discussed in *Zenith*, the court is unwilling to venture beyond the Lanham Act precedent of this Circuit.